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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,522	04/16/2004	Geert Plaetinck	D0590.70011US02	2890

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,522	PLAETINCK ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-41,55 and 57-79* is/are pending in the application.

4a) Of the above claim(s) *55,57-69 and 75-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-41 and 70-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 5/7/07 was entered for the purpose of a compact prosecution, even though the term "nemaktode" in presently presented claim 73 is misspelled. It is noted that the previously presented claim 73 in the Amendment filed on 10/18/06, the proper term "nematode" is recited.

Claims 30-41, 55, 57-79 are pending in the present application.

Claims 55, 57-69 and 75-79 were withdrawn previously from further consideration because they are directed to a non-elected invention.

Accordingly, claims 30-41 and 70-74 are examined on the merits herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30, 32-34, 39-41, 70-71 and 74 are still rejected under 35 U.S.C. 102(b) as being anticipated by Alderete (US 5,679,551) for the same reasons already set forth in the Office Action mailed on 1/8/07 (pages 4-5). ***The same rejection is restated below.***

Alderete already taught the cloning of a satellite dsRNA s1 or s1' into the pGEM4Z vector containing T7 and SP6 promoters, and the recombinants were transformed into competent *E. Coli* JM109 cells (see at least example 5, particularly col. 18, lines 10-38). Due to the vagueness of the term "derived from", the cDNA sequence encoding the satellite dsRNA s1 or s1' can be considered to be a derivative of a DNA sequence derived from *C. elegans* or from a pest.

The transformed *E. Coli* JM109 cells containing a pGEM4Z vector containing a cDNA sequence encoding the satellite dsRNA s1 or s1' are indistinguishable from a micro-organism as broadly claimed. Additionally, please, also note that where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the **PTO's inability to manufacture products or to obtain and compare prior art products**. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the reference anticipates the instant claims.

Response to Arguments

Applicant's arguments related to the above rejection in the Amendment filed on 5/7/07 (pages 10-11) have been considered but they are respectfully not found persuasive for the following reasons.

Applicants argue basically that the DNA sequence described in US 5,679,551 is not a DNA sequence that is obtained from *C. elegans* or a pest, and therefore the rejection should be withdrawn.

Please note that the rejected claims do not recite that a DNA sequence is obtained from *C. elegans*. With respect to the issue whether the DNA sequence is obtained from a pest, please note that the cDNA sequence encoding the satellite dsRNA s1 or s1' found in *Trichomonas vaginalis* parasite that causes trichomoniasis, a common sexually transmitted infection in human, and therefore it still falls within the broad scope of a DNA sequence obtained from a pest.

Accordingly, claims 30, 32-34, 39-41, 70-71 and 74 are still rejected under 35 U.S.C. 102(b) as being anticipated by Alderete (US 5,679,551) for the reasons set forth above.

Claims 30-41 and 70-74 are still rejected under 35 U.S.C. 102(b) as being anticipated by Timmons et al. (East Coast Worm Meeting Abstract 180, May 12, 1998; IDS) as evidenced by Timmons et al. (Nature 395:854, 1998; IDS) for the same reasons already set forth in the Office Action mailed on 1/8/07 (pages 5-6). ***The same rejection is restated below.***

Timmons et al. (East Coast Worm Meeting Abstract 180) disclosed that bacteria expressing GFP or unc-22 dsRNA being fed to myo3::GFP worms or *C. elegans*, and a reduction in muscle cell GFP expression was observed in animals fed bacteria expressing dsGFP RNA while animals grown on bacterial expressing unc-22 RNA showed no loss of GFP expression but they exhibited a weak twitching phenotype. The used bacteria expressing GFP or unc-22 dsRNA are *E.Coli* containing a plasmid vector designed for bidirectional transcription by bacteriophage T7 RNA polymerase as evidenced by the teachings of Timmons et al. (Nature 395:854, 1998; IDS) describing the same studies.

Additionally, please, also note that where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the **PTO's inability to manufacture products or to obtain and compare prior art products**. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the reference anticipates the instant claims.

Response to Arguments

Applicant's arguments related to the above rejection in the Amendment filed on 5/7/07 (pages 10-11) have been considered but they are respectfully not found persuasive for the following reasons.

Applicants argue basically that there is no evident connection between what is disclosed in Timmons et al. Abstract and Timmons et al. article, because there is nothing in either the Timmons et al abstract or the Timmons et al article to suggest that the methods and materials used in the abstract are the same as those described in the article.

The connection between the Timmons et al. Abstract and Timmons et al. article is **the description of the same results obtained by "feeding bacteria expressing GFP or unc-22 ds RNA to myo3::GFP worms" by the same group of people.**

Once again, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the **PTO's inability to manufacture products or to obtain and compare prior art products**. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, claims 30-41 and 70-74 are still rejected under 35 U.S.C. 102(b) as being anticipated by Timmons et al. (East Coast Worm Meeting Abstract 180, May 12,

1998; IDS) as evidenced by Timmons et al. (Nature 395:854, 1998; IDS) for the reasons set forth above.

Claims 30, 32-39 and 70-74 are still rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al. (US 6,506,559 B1 with an effective filing date of 12/23/1997; IDS) for the same reasons already set forth in the Office Action mailed on 1/8/07 (pages 6-7). ***The same rejection is restated below.***

With respect to the embodiments with an effective filing date of 12/23/1997, Fire et al already disclosed an *ex vivo* or *in vivo* process of introducing an RNA into a living cell to inhibit gene expression of a target gene in that cell, wherein the RNA has a region with double-stranded structure and that the cell can be a plant, an animal, a protozoan, a virus, a bacterium or fungus cell (see at least Summary of the Invention). Fire et al further teaches that RNA may be synthesized either *in vivo* or *in vitro*, and cloned RNA polymerase can be used for transcription *in vivo* or *in vitro* or endogenous RNA polymerase of the cell may mediate transcription *in vivo* (col. 4, lines 62-67; col. 7, lines 42-52; col. 8, lines 13-19). Fire et al further discloses that for transcription from a transgene *in vivo* or an expression construct, a regulatory region may be used to transcribe the RNA strand or strands. Fire et al further teaches that the RNA may be synthesized by a cellular RNA polymerase or a bacteriophage RNA polymerase such as T3, T7 and SP6 (col. 8, line 62 continues to line 25 of col. 9). An exemplified dsRNA is unc-22 dsRNA.

The teachings of Fire et al meet every limitation of the instant claims. Therefore, the reference anticipates the instant claims.

Response to Arguments

Applicant's arguments related to the above rejection in the Amendment filed on 5/7/07 (page 11) have been considered but they are respectfully not found persuasive for the following reasons.

Applicants argue basically that in the priority document (60/068,562) of the Fire patent, the cited passage on *in vivo* or *in vitro* production of dsRNA was intended for demonstrating how dsRNA could be produced and that throughout the priority document it is evident that the "fate" of the dsRNA is for "injection" in *C.elegans*. Therefore, there is nothing in the Fire provisional application that provides the claimed micro-organism of the present invention.

It is noted that the concept of injecting dsRNA in *C.elegans* is only a specific embodiment taught in the priority document of the Fire patent. The priority document also states that "**Physical methods of introducing nucleic acids are preferred such as for example**, injection of a solution containing the RNA, bombardment by particles covered by the RNA, soaking the cell or organism in a solution of the RNA, or electroporation of cell membranes with the RNA. **A viral vector packaged into a viral particle would accomplish both efficient introduction of an expression vector into the cell and transcription of RNA encoded by the expression vector**" (page 12, lines 7-12) and "The cell with the target gene may be derived from or contained in any

organism (e.g., plant, animal, fungus or yeast). **RNA may be synthesized either *in vivo* or in vitro**. Endogenous RNA polymerase of the cell may mediate transcription *in vivo*, or cloned RNA polymerase can be used for transcription *in vivo* or *in vitro*. **For transcription from a transgene in vivo or an expression vector, a regulatory region (e.g., promoter, enhancer, silencer) is used to transcribe the RNA strand(s)**" (page 7, lines 10-15).

Accordingly, claims 30, 32-39 and 70-74 are still rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al. (US 6,506,559 B1 with an effective filing date of 12/23/1997; IDS) for the same reasons set forth above.

Conclusions

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

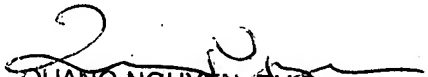
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.



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